Charles M. Lizza
William C. Baton
SAUL EWING ARNSTEIN & LEHR LLP
One Riverfront Plaza, Suite 1520
Newark, New Jersey 07102-5426
(973) 286-6700
clizza@saul.com

Attorneys for Plaintiff
Shire US, Inc.

Of Counsel:

Michael F. Brockmeyer
David S. Shotlander
Amanda J. Hamilton
HAUG PARTNERS LLP
1667 K St. NW, Suite 500
Washington, DC 20006
(202) 292-1530
mbrockmeyer@haugpartners.com

Fred A. Kelly, Jr.
Joshua S. Barlow
HAUG PARTNERS LLP
One Post Office Square
Boston, MA 02109
(617) 426-6800
fkelly@haugpartners.com

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SHIRE US, INC., Plaintiff, v. ALLERGAN, INC., ALLERGAN SALES, LLC, and ALLERGAN USA, INC., Defendants.	**Civil Action No. 2:17-cv-07716-JMV** **SECOND AMENDED COMPLAINT** **(Filed Electronically)** **REDACTED PUBLIC VERSION**

NATURE OF THE ACTION

1. Plaintiff Shire US, Inc. ("Shire") brings this suit against defendants Allergan, Inc., Allergan Sales, LLC, and Allergan USA, Inc. (collectively, "Allergan") to permanently enjoin, and recover money damages resulting from, Allergan's ongoing, overarching, and interconnected anticompetitive scheme to monopolize the market for prescription drugs for treatment of dry eye disease ("DED") available to patients through Medicare Part D prescription drug plans. Those

plans provide elderly, low-income, and other vulnerable members of society with government-subsidized prescription drug coverage. Part D patients do not consider commercial prescription drug coverage or paying cash for their prescription drugs to be an adequate substitute for Part D coverage. Allergan's anticompetitive scheme has caused and is causing injury to Part D patients with DED because those patients are being forced to pay more money to treat their DED with a sixteen-year-old and clinically inferior Allergan drug – Restasis®. Allergan's anticompetitive conduct is also denying these patients access to Xiidra® – Shire's best-in-class, breakthrough drug to treat DED. Through a combination of anticompetitive bundling and exclusive dealing arrangements, Allergan is coercing Part D plans representing over 70 percent of the Part D market for prescription DED medications to effectively exclude Xiidra from, or severely restrict Xiidra on, their formularies, while at the same time maintaining Restasis on a "preferred" formulary tier. In fact, Allergan has boasted that its scheme has "blocked" Xiidra on Part D formularies, which is borne out by the fact that Restasis has maintained a market share of nearly 87 percent despite the entry of Xiidra into the Part D market nearly 3 years ago. Allergan's unlawful and anticompetitive conduct has effectively denied and will continue to effectively deny Part D patients access to Xiidra, a clinically unique and effective drug (that many doctors believe is superior to Restasis), and otherwise provide Part D beneficiaries with far less access to DED medications than commercial plan beneficiaries have.

2. Allergan's scheme also has severely limited and will continue to limit the growth of the Part D market for DED medications. Restasis is approved to treat a limited subset of the DED population. Xiidra, on the other hand, is approved to treat all of the signs and symptoms of DED and, therefore, can be prescribed to treat a much larger population of DED patients. Thus, by virtue of a broader indication alone, Xiidra will increase the number of Medicare beneficiaries

prescribed DED medications and grow the Part D market. Restricting patients to Restasis, as Allergan has done, will prevent that growth.

3. Moreover, Allergan's scheme does not save patients any money. To the contrary, because Restasis must often be used in conjunction with a topical prescription steroid, Allergan's plot to restrict patients' access to Xiidra (which has the same list price as Restasis and does not require the use of any additional drugs) has only increased patients' costs.

4. Allergan's anticompetitive conduct in maintaining its monopoly power in the Part D market for DED patients not only injures Part D patients with DED, it also injures Shire by denying it sales of Xiidra that, but for Allergan's anticompetitive conduct, would have been dispensed to Part D patients with DED.

5. Restasis is a vital component of Allergan's product portfolio. From 2016 to 2018, Restasis was Allergan's second highest revenue-producing drug (behind Botox®), with net sales of $4.2 billion that accounted for over 9 percent of Allergan's total net revenue of $46.3 billion during that period.

6. While it is a mature "cash cow" for Allergan, Restasis is not an innovative product. It features an active ingredient, cyclosporine, that was developed in the 1970s as an immunosuppressive agent to prevent organ rejection in organ transplant patients. It was later re-purposed as a drug to treat psoriasis and rheumatoid arthritis. When Allergan sought regulatory approval for the use of cyclosporine to treat DED, it faced significant challenges. Allergan's new drug application was pending for years before the United States Food & Drug Administration ("FDA") finally approved Restasis (after it was rejected by an advisory committee due to a lack of efficacy). When it did so, the FDA only approved Restasis for a

narrow subset of the DED patient population – patients with reduced tear fluid volume – a sign of DED found in only a small (about 10 percent) proportion of DED patients.

7. Since Restasis' commercial launch, many patients taking Restasis have experienced ocular burning and other adverse reactions. Many other patients have found that Restasis did not provide any relief for their DED conditions, even after using Restasis for months. Indeed, in clinical trials, Restasis showed only marginal clinical benefit among a small subset of the study population after six months of use. Since its approval, nearly half of the patients taking Restasis stopped taking the medication within six months of it being prescribed.

8. Nevertheless, from 2002 until September 2016, Restasis was the only prescription drug available to patients in the United States who suffer from DED. Facing no competition, Restasis enjoyed increasing prices and a complete monopoly on the "preferred" tier of Part D plan formularies.

9. In 2016, however, Allergan faced a profound shift in the landscape for Restasis. In July of that year, the FDA approved Xiidra, an event the investing public perceived as a "key competitive threat[] [to] Allergan."[1] Unlike Restasis, Xiidra is a new and highly innovative molecular entity that was specifically developed to treat ocular conditions. In clinical studies, patients taking Xiidra experienced relief from the symptoms of DED within as little as two weeks and, from the underlying inflammatory conditions which cause DED, within 6 to 12 weeks. As a result, the FDA approved Xiidra for an expansive indication – the treatment of both the signs and symptoms of DED – which applies to all patients who suffer from DED.

[1] "Allergan's Restasis Faces Dry Eye Threat: Examining Xiidra's Initial Sales Trends" (available at https://seekingalpha.com/article/4020912-allergans-restasis-faces-dry-eye-threat-examining-xiidras-initial-sales-trends).

10. Since Xiidra's launch in August 2016, the medical community and DED patients have enthusiastically greeted Xiidra's entry into the marketplace because they finally have a choice of DED prescription treatments and that choice includes a better drug. Indeed, Shire has quickly gained favorable formulary position and market share in the separate market represented by commercial prescription drug plans, where Shire is able to compete on a level playing field and physicians as well as DED patients can choose between Restasis and Xiidra. In the time since its launch, Xiidra has been prescribed to approximately 38 percent of commercial plan beneficiaries who are prescribed DED medications.

11. However, on Part D plans, which participate in a market unto themselves, Allergan still has the market cornered. That is because Allergan has exploited Part D market dynamics through a scheme of anticompetitive, coercive, unfair, and deceptive conduct with the objective of maintaining its $1-plus billion-dollar-a-year monopoly for as long as possible. In carrying out this scheme, Allergan has compelled and coerced Part D plans, in whole or in part, to exclude Xiidra from, or severely restrict Xiidra on, their formularies. Allergan's actions have caused injury to Part D patients with DED by forcing them to buy a lower quality product with a higher overall cost and depriving them of a superior product at a lower overall cost. The Part D plans have done this at Allergan's behest, despite Xiidra's clinical advantage in improving both the signs and symptoms of DED and despite the fact that Shire has offered Part D plans equal or greater rebates on Xiidra than Allergan has offered on Restasis.

12. As a result of Allergan's actions, more than two years after Xiidra's launch, Restasis still comprises approximately 87 percent of the DED drugs dispensed to Part D patients, while Xiidra comprises only around 13 percent. That will be the case as long as Allergan's scheme is allowed to continue.

13. Medicare beneficiaries covered under Part D have limited choice in the prescription medications available to them because Part D plans cover only certain treatments for each drug class listed on their formularies, and the plans decide which medications are on the formularies. Because for many years Restasis was the only FDA-approved DED medication, Restasis was the only choice plans offered on their formularies.

14. Confronted by a superior drug with equal or better pricing and the threat of substantial loss of Restasis' market share, Allergan set a scheme in motion to prevent Part D beneficiaries' access to and use of Xiidra and to preserve Allergan's monopoly in the Part D market.

15. Allergan boasted to its investors in early 2017 that "Restasis and other dry eye products will run through Medicare Part D. And today, we have 95 percent coverage . . .[and] the picture in '18 is going to look comparable." In mid-2017, Allergan's CEO went so far as to state publically that Allergan has blocked Shire from the Part D market. Allergan has and continues to maintain its disproportionately high market share of Part D patients by employing egregiously anticompetitive and unlawful tactics that it has concealed from Part D patients and from Shire.

16. As part of its scheme, Allergan has offered and paid and continues to offer and pay anticompetitive product discounts and rebates to Part D plans, including rebates bundled across several Allergan drugs on Part D formularies, to coerce Part D plans to exclude Xiidra from their formularies. Allergan is able to coerce Part D plans to exclude Xiidra despite Xiidra's clinical benefits and the more favorable financial terms Shire has offered compared to Allergan's rebates on Restasis because, if they included Xiidra on their formularies, the plans would immediately lose substantial discounts and/or rebates across a large portfolio of Allergan drugs.

The loss in value of Allergan's portfolio-wide discounts and/or rebates to the Part D plans is so substantial that it is impossible for Shire, which does not have a Part D product portfolio with sufficient sales or utilization to compete with Allergan's, to gain formulary access for Xiidra, no matter what financial terms it offers. Shire has offered the Part D plans discounts and/or rebates far exceeding the discount rates on Xiidra that Shire has agreed to provide commercial prescription drug plans in exchange for listing Xiidra on the commercial plans' formularies. Nevertheless, the Part D plans rejected Shire's offers, resulting in continued harm to Part D patients and Shire's ongoing loss of sales and profits that it would have obtained but for Allergan's exclusionary scheme.

17. The stark impact of Allergan's wide-ranging bundled discounts was bluntly summarized by one plan during negotiations in 2017, when its representative told Shire that– "You could give [Xiidra] to us for free, and the numbers still wouldn't work." This anticompetitive barrier has remained in place for as long as Xiidra has been on the market, as shown during negotiations between Shire and the same plan in 2018, when Shire was rebuffed again. Why? Because Shire did not have products on which it could provide discounts in addition to its proposed discounts on Xiidra that would be sufficient to offset the plan's loss of Allergan's bundled discounts.

18. Consequently, in sharp contrast to the commercial plan formularies where Shire has already captured approximately 38 percent market share, Allergan's bundled rebates and exclusive contracts with the Part D plans effectively foreclose Shire (an equally efficient competitor to Allergan) from competing in the Part D market.

19. Allergan also directly interfered with and caused the abandonment of an agreement that Shire was finalizing with an administrator of several Part D plans. During

negotiations in 2017 for formulary placement in 2018, the plan administrator first told Shire that changing from Restasis to Xiidra would cause no disruption to the plans or patients, the administrator (after conferring with Allergan) later told Shire that listing Xiidra on the plans' formularies would be "too disruptive" and, therefore, would not agree to list Xiidra on the formularies. When Shire asked the plans to reconsider, the administrator told Shire that Allergan's contract with the plans would not allow Xiidra on the formulary. When Shire asked "how do we get out" of this position in the future, the administrator replied tersely, "you don't."

20. Nothing changed during negotiations in 2018 for formulary placement in 2019. In furtherance of the anticompetitive arrangement that Plan 3 reached with Allergan for the prior year, Plan 3 refused again to consider placing Xiidra on its formulary, and indicated that Shire could seek access to its formulary only after a Restasis generic has entered the market.

21. The date when a generic Restasis product will enter the market is unknown, and Allergan has done everything within its power to delay that date for as long as possible. Examples of such conduct can be found in the allegations from separate litigation brought against Allergan by purchasers and certain end payors of Restasis. *See, e.g.*, End-Payor Am. Compl., *In Re: Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litigation*, 1:18-md-02819 (E.D.N.Y. Dec. 20, 2018), ECF No. 210.

22. The plan administrator's blunt message leaves no doubt that Allergan has coerced the plans and others not to deal with Shire regardless of Shire's superior product and financial offerings, and will continue to prevent Shire from executing agreements with these plans and getting Xiidra on their formularies well into the future without regard to Shire's financial offerings. This exclusion of Xiidra harms Part D patients, Shire, and competition.

23. Allergan's conduct has substantial and detrimental effects on Medicare Part D patients – who, because DED has a higher prevalence among the elderly, represent a disproportionately large, and growing, segment of the DED patient population – and it harms competition.

24. Allergan's scheme not only denies Part D patients access to Xiidra, it has and will reduce the overall size and growth of the Part D market for DED treatments because Restasis has a much narrower indication than Xiidra and is approved to treat only a small subset of DED patients. Perhaps most importantly, this scheme has not and will not lower the price that patients prescribed Restasis pay in premiums under the Part D plans, lower their copayments under the Part D plans, or provide those patients with any other benefit. Only Allergan will benefit from its scheme.

25. Patients prescribed Xiidra who are beneficiaries of Part D plans that have not placed Xiidra on their formularies have suffered and will suffer an even worse fate. Before those plans will offer coverage for Xiidra, patients must pursue an onerous appeals process, which typically requires them to demonstrate that they either tried Restasis and it was ineffective, or that its side effects were so severe that they cannot tolerate taking the medication. Even if their appeals are granted and coverage is extended, all of those patients will still pay an amount in copayments that is ***two to five times higher*** than they otherwise would if Xiidra's formulary status was in parity with Restasis. The combination of the appeals process and significantly higher copayments (which some patients are unable to pay) has deprived and will effectively deprive those patients access to a clinically superior product.

26. Allergan's scheme also stifles market output. As a result of Shire's efforts to better educate the physician and patient communities about DED, since Xiidra's launch the total

amount of prescriptions in the commercial plan market for DED has increased for both Xiidra and Restasis (despite its clinical inferiority). That is not occurring in the Part D plan market, where dispensing of Restasis has remained flat.

27. Allergan's product discounts and bundled rebates do not benefit Part D patients because those discounts and rebates force them to use an inferior DED drug, deprive them of a superior DED drug, and cause them to pay higher costs for their DED treatment, all of which is due to the exclusion of Xiidra from Part D plans caused by Allergan's anticompetitive conduct. Shire is also injured by Allergan's conduct, and that injury flows directly from, and is inextricably intertwined with, the injury that Allergan's conduct causes to Part D patients.

28. Because of Allergan's exclusionary conduct, Xiidra's Part D plan market share will not rise significantly from where it is today – around 13 percent – while Restasis' share will continue to be at or near 87 percent. This conduct, when combined with the barriers to entering the DED market, allows Allergan to maintain its monopoly.

29. If Allergan's conduct is allowed to continue, despite Xiidra's superiority, physicians and patients will eventually become conditioned to prescribe and use only Restasis, which will cause Xiidra to be limited to a very small segment of the Part D market. Because the incidence of DED is most prevalent in older patients, as the population ages, more and more DED patients will be covered by Part D plans. The exclusion of Xiidra from the Part D market, and the resulting conditioning of physicians and patients to the prescription and use of clinically inferior Restasis, will further solidify Allergan's monopoly, cause more harm to more patients, and effectively exclude Shire from the fastest growing – and one day largest – market for DED drugs. At that point, Allergan will no longer need to offer the level of discounts and rebates that

it is now offering and will reduce those discounts and rebates – thereby "raising" prices in order to recapture its "investment" in its anticompetitive scheme. This is classic monopoly conduct.

30. As evidenced by the fact that Xiidra achieved approximately 38 percent of the commercial plan market share within the first three years of its launch, when Shire has had a level playing field to compete with Restasis, physicians and patients have chosen Xiidra. Quite simply, Allergan has and will continue to use bundled discounts, exclusive dealing, coercion and interference to unlawfully "block" Shire from competing with it, directly causing financial harm to Shire and permitting Allergan to maintain its monopoly in the Part D market at all costs and at the expense of Part D beneficiaries until Xiidra is effectively eliminated as a competing product in the Part D market.

31. Allergan's unlawful conduct has caused, and threatens both Shire and consumers with, loss or injury in violation of the federal antitrust laws, specifically Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1-2, as well as applicable state law. Shire seeks money damages and injunctive relief, as well as its reasonable attorneys' fees and costs of prosecuting this action, under Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15 and 26, and applicable state law.

THE PARTIES

32. Shire is a New Jersey corporation with its principal place of business and headquarters at 300 Shire Way, Lexington, Massachusetts 02421. Shire is a pharmaceutical company that develops, manufactures, markets, and distributes branded and generic pharmaceutical products worldwide. On January 8, 2019, Takeda Pharmaceutical Company Limited acquired Shire plc, the global parent of Shire.

33. Allergan, Inc. is a Delaware corporation that conducts business in this District. Allergan, Inc. has a principal place of business located at 400 Interpace Parkway, Parsippany, New Jersey 07054.

34. Allergan Sales, LLC is a Delaware limited liability company registered to conduct business in New Jersey. Allergan Sales, LLC conducts business in this District. Allergan Sales, LLC has a principal place of business located at 2525 Dupont Drive, Irvine, California 92612.

35. Allergan USA, Inc. is a Delaware corporation registered to conduct business in New Jersey. Allergan USA, Inc. conducts business in this District. Allergan USA, Inc. has a principal place of business located at 2525 Dupont Drive, Irvine, California 92612.

36. Allergan, Inc., Allergan USA, Inc., and Allergan Sales, LLC are specialty pharmaceutical companies engaged in the research, development, manufacture, sale, distribution, and marketing of ophthalmic, medical aesthetics, biosimilar, and over-the-counter pharmaceutical products.

JURISDICTION, VENUE, AND INTERSTATE COMMERCE

37. This Court has subject matter jurisdiction pursuant to 15 U.S.C. §§ 15 and 26, and 28 U.S.C. §§ 1331 and 1337. Shire brings this action pursuant to Section 16 of the Clayton Act and applicable state law, to obtain money damages, equitable relief, costs of suit, and reasonable attorneys' fees for Allergan's violations of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1-2, as well as applicable state law.

38. Venue is proper in this District under Section 12 of the Clayton Act, 15 U.S.C. § 22, and under 28 U.S.C. § 1391(b) and (c). For venue purposes, the defendants can be found in and transact business in this District. Allergan's anticompetitive scheme has impacted and will impact Shire and Medicare Part D beneficiaries in this District, and elsewhere.

39. Allergan's misconduct occurs in and affects interstate commerce, as Allergan has contracted Medicare Part D plans for Restasis' formulary coverage, and foreclosed Xiidra from the same, throughout the United States. Both Restasis and Xiidra are manufactured and shipped

in interstate commerce, and Allergan's anticompetitive conduct directly affects the price and volume of drugs shipped in interstate commerce.

BACKGROUND

Dry Eye Disease

40. Dry eye disease (DED) occurs when the eye does not produce tears properly or when tears are not of the correct consistency and/or evaporate too quickly, and it is characterized by inflammation and damage to the ocular surface, resulting in blurry or fluctuating vision, as well as eye fatigue. Studies show that only about 10 percent of DED patients exhibit a lack of tear production; the remaining 90 percent of DED cases have one or more different causes of the disease.

41. DED has serious detrimental effects for many patients and is one of the most common reasons patients visit an eye care professional. DED causes decline in quality of life, increased depression, decrease in work productivity, both absenteeism and presenteeism, and impairment of reading, watching television, and computer use. DED results in ocular surface damage, which may also adversely affect cataract and refractive surgical outcomes, as well as patients wearing contact lenses. DED is thought to be a chronic, progressive condition, and early intervention is thought to forestall the disease from worsening. Failure to administer timely treatment could lead to increased inflammation, significant damage to the eye (including scarring), and complications including vision loss.

42. DED can result in significant costs to patients, providers, and the overall healthcare system. Nearly 30 million Americans are afflicted with symptoms of DED, which are among the most common complaints patients report to eye care professionals, and an estimated 16.4 million Americans report a DED diagnosis from a physician. Nevertheless, only about 1 million patients currently receive prescription treatment for DED, which has created a large

disparity between diagnosed and treated patients. As a result, DED remains an area of significant unmet need.

43. That is particularly true among patients eligible for Medicare. Because it is a condition that progresses with age, DED disproportionately affects the elderly. According to one study, the prevalence of DED among adults over the age of 65 is estimated to be between 11 and 12 percent. Thus, more than five million Medicare beneficiaries may suffer from DED. And, the need for prescription DED treatment is only expected to increase due to the aging U.S. population and the increased rates of digital device use (screen time) across all age groups.

Prescription Drugs for the Treatment of DED

44. Restasis and Xiidra are the only FDA-approved prescription drugs available to patients suffering from DED, although the indications they are approved to treat are very different in scope. As discussed in greater detail below, the FDA has approved Xiidra to treat both the signs and symptoms of DED (including underlying inflammation), while Restasis is approved merely to treat a specific sign of DED – reduced tear fluid volume – that affects only about 10 percent of the patients suffering from DED.

45. In August 2018, Sun Pharmaceuticals announced that the FDA had approved its new prescription DED treatment, Cequa® (cyclosporine ophthalmic solution), but as of April 2019, Sun has yet to commercially launch Cequa. The barriers to entry that Allergan erected as to Xiidra, described herein, apply equally to Cequa.

46. In 2002, three years after Allergan filed its new drug application and worked its way through a complicated and problem-laden approval process, the FDA approved Restasis for commercialization in the U.S. Restasis is a cyclosporine (immunosuppressive agent) indicated to increase tear production in patients suffering from ocular inflammation associated with chronic DED. The FDA approved Restasis despite the fact that Restasis demonstrated only marginal

clinical benefit six months after administration in clinical studies, without evidence of symptomatic improvement. In fact, an FDA advisory committee recommended that the FDA not approve Restasis for commercialization due to a lack of efficacy.

47. Since Allergan launched Restasis, patients taking Restasis have experienced ocular burning (an experience which 17 percent of Restasis clinical study patients reported). These and other adverse reactions have led to tolerability issues and relatively high rates of patients discontinuing Restasis as a medication. According to one study, nearly a quarter (23 percent) of Restasis users discontinued treatment within three months, while nearly half (43 percent) discontinued use of Restasis within six months. Thus, a significant number of patients appear to stop using Restasis before clinical studies show it becomes effective, which is typically ***after*** six months of use.

48. In an attempt to enhance tolerability and effectiveness, many physicians prescribing Restasis place their patients on an induction treatment with a low potency corticosteroid, which includes the administration of a topical steroid (*e.g.*, Lotemax) before receiving Restasis as an adjunctive treatment. These additional medications increase the cost of Restasis therapy to the patient. Steroid use is also a risk factor for cataract formation, glaucoma, corneal thinning, and corneal infections, especially when used chronically.

49. The FDA approved Xiidra in July 2016. Before that approval, though several drug companies had sought FDA approval for other DED prescription medications, Restasis remained the only prescription treatment for DED on the market.

50. Prior to approval, the FDA granted Xiidra priority review, which the agency reserves only for those drugs that it believes can provide "a significant advance in clinical care." The FDA also designated Xiidra as a first-in-class, novel drug, stating: "A small subset of these

new approvals, referred to as novel drugs, are among the more innovative products that often help advance clinical care to another level."

51. Xiidra also had the largest clinical trial registration program for an investigational DED candidate. The program included four clinical trials which enrolled over 2,200 patients. In those clinical studies, Xiidra provided relief from symptoms of DED in as early as two weeks of dosing and demonstrated clinical benefits in treating the signs of DED within 12 weeks of dosing. Restasis, by comparison, demonstrated only a marginal clinical benefit among a small subset of its study population after six months of administration.

52. Unlike Restasis, which has cyclosporine-A as an active ingredient (an immunosuppressive agent developed four decades ago for use in organ transplant patients), Xiidra was developed purposefully for use in the eye. As the FDA recognized in a July 12, 2016 press release, "Xiidra is the first medication in a new class of drugs, called lymphocyte function-associated antigen 1 (LFA-1) antagonist" that is thought to inhibit T-cell adhesion to ICAM-1 (a type of transmembrane protein) and the secretion of inflammatory cytokines, interrupting the perpetual cycle of inflammation.

53. Xiidra is also the first prescription medication broadly approved by the FDA to treat ***both*** the signs and symptoms of DED (including inflammation), unlike Restasis, which only increases tear production and only treats a subset of DED patients with a specific sign of the disease (reduced tear fluid volume).

54. Consequently, many physicians, academics, and other thought leaders have recognized Xiidra as a significant advancement and a clinically superior product to Restasis. As Dr. Christopher Rapuano, an ophthalmology professor and author, put it succinctly, Xiidra is a "big game changer."

55. Despite Xiidra's status as an innovative new class of medication and its expansive indication, and despite Shire's conviction that Xiidra is clinically superior, Shire elected not to set a higher list price for Xiidra than Allergan set for Restasis.

56. Absent Allergan's unlawful and anticompetitive conduct, Xiidra would significantly advance the level of clinical care for DED available to Part D beneficiaries at no additional cost to patients.

Medicare Part D

57. Congress established Medicare in 1965 under Title XVIII of the Social Security Act to provide health insurance to people age 65 and older regardless of income. Since its inception, Medicare has been amended to expand benefits and increase the eligibility pool. Today, the program helps more than 55 million people age 65 and older and younger people with permanent disabilities pay for healthcare services.

58. Medicare benefits are divided into four parts. Parts A and B are traditional Medicare, where a beneficiary can see any doctor and hospital that takes Medicare and the government pays directly for the healthcare services a patient receives. Part C is also known as Medicare Advantage, which allows beneficiaries to enroll in a private health plan as an alternative to traditional Medicare. These plans receive payments from Medicare to provide all Medicare-covered benefits.

59. Part D is the optional outpatient prescription drug program, which was authorized by the Medicare Prescription Drug, Improvement, and Modernization Act (P.L. 108–173). Then Senate Majority Leader Bill Frist, one of the initiative's chief negotiators, hailed its passage: "Today is a historic day and a momentous day. Seniors have waited 38 years for this prescription drug benefit to be added to the Medicare program. Today they are just moments

away from the drug coverage they desperately need and deserve."[2] Part D is available to all Medicare beneficiaries enrolled in traditional Medicare. In 2016, an estimated 40.8 million beneficiaries were enrolled in Part D.

60. The Centers for Medicare & Medicaid Services ("CMS") contracts with private companies, known as Part D plan administrators, to provide drug coverage to the beneficiaries who chose to enroll in the program. Part D plan beneficiaries generally pay a monthly premium and cost sharing for prescriptions (varying by plan). Premiums cover around 25.5 percent of the cost of standard coverage for all beneficiaries enrolled in Part D, and government subsidies cover the remainder.

61. Part D plans must offer either at least standard prescription drug coverage, as defined in the Medicare Prescription Drug, Improvement, and Modernization Act, or "alternative prescription drug coverage with at least actuarially equivalent benefits and access to negotiated prices," which must be approved by the Secretary of Health and Human Services. Within these parameters, each plan is free to decide which specific drugs it will cover. The list of drugs covered by a particular plan is called its "formulary."

62. Part D formularies are the critical access point for the prescription drugs that Part D patients receive. The formularies stand between the patients and the doctors, the patients and the pharmaceutical companies, and the doctors and the pharmaceutical companies. They control patient and doctor access to prescription drugs and, in turn, a pharmaceutical company's access to patients. Having that access is crucial to the success of a prescription drug.

63. Each formulary is organized into drug categories (*e.g.*, cancer drugs). Within each category, drugs are then listed by class according to similarities in their chemical structures,

[2] Pear R., Hulse C., "Senate Removes Two Roadblocks to Drug Benefit," New York Times, 2003:A1, Nov. 25.

mechanisms of action (*e.g.*, beta blockers), or use in treating the same disease. Medicare regulations require that each formulary include at least two Part D drugs within each therapeutic class and category as defined by their prescription drug plans.

64. DED prescription drugs are in a catch-all category of "Ophthalmic Agent Other," because the third-party compendia that CMS relies upon for drug classification have not yet established DED as its own category. Therefore, Part D formularies only have to cover two ophthalmic agents, but as a practical matter virtually all Part D plans cover at least one DED drug.

65. The regulatory framework governing the composition and operation of Part D plan formularies does not apply to commercial prescription drug plans.

DED Treatment For Patients With Coverage From Part D Plans

66. Prescriptions covered under Part D plans represent over 40 percent of all prescriptions for DED treatment. Access to a Part D plan's drug formulary is critical to the success of prescription DED treatments because the treatments are almost exclusively distributed to individual patients and caregivers as opposed to being provided by a healthcare provider in, for example, a hospital setting. Denying or restricting access to such a large number of prescriptions deters market entry as well as investment in DED prescription treatments generally. Thus, having access to Part D formularies is crucial to a pharmaceutical company selling a drug treating DED, and it is crucial for Medicare beneficiaries' access to treatment.

67. When faced with a choice among alternative treatment options for a given indication, there is a strong incentive for prescribing physicians and patients to choose the treatment that is covered (*i.e.*, listed on the Part D plan's drug formulary as the preferred drug and typically in the payment tier with the lowest copayment) to minimize the costs and burdens of, for example, seeking individual approval or reimbursement for an off-formulary treatment. A

drug's market access is based almost entirely on a pharmaceutical company's agreements with Part D plans to have its drugs listed on the plans' formularies at agreed-upon pricing, discounts, and/or rebates.

68. Physicians who treat Part D patients become conditioned to prescribing drugs that they know are covered on most Part D formularies and avoid drugs that are frequently not covered. As the Part D market grows, this effect becomes more substantial and ingrained. Thus, a pharmaceutical company can obtain or maintain a monopoly in the Part D market by erecting entry barriers through anticompetitive arrangements that exclude a competitor's drug from Part D formularies. Such agreements provide formulary exclusivity to the company's drug thereby excluding new, competing drugs from entering the Part D market. The harm to Part D patients and potential competitors will only increase over time as Part D plans and Part D patients become the predominant purchasers and consumers of prescription drugs for diseases that disproportionately afflict the elderly – like DED.

69. Pharmaceutical companies do not sell their drugs to Part D plans, but rather, Part D plans reimburse pharmacies for the dispensing of covered drugs to plan participants. Part D plans will only reimburse for drugs that they include on the plan formularies or for which they grant an "exception." As explained below, those exceptions are typically granted only after a successful appeal has been filed by the plan participant or his/her physician.

70. Almost all Part D patients are in plans with tiered formularies. Each tier corresponds to the cost-sharing or copayment that most participants of that plan will pay for the drugs on that tier, and whether the participant needs to seek and obtain a prior authorization or an exception to have coverage of those drugs. With respect to Part D formularies, brand drugs are typically categorized as "preferred," "non-preferred," "not covered," or "specialty." Except for

certain Medicare beneficiaries receiving a low-income subsidy who pay the same copayments regardless of tier/preference, Part D patients pay a lower copayment for preferred drugs and a higher copayment for non-preferred drugs.

71. Between 2006 and 2016, most Part D plans required a copayment of between $27 to $41 for branded drugs in the preferred formulary tier, and the median coinsurance rate was 20 percent. For non-preferred drugs, most patients pay a copayment of $100 (and as much as $220) or pay coinsurance at a rate of at least 40 percent (and as much as 50 percent). Non-preferred drugs, therefore, gain far fewer sales under Part D plans than preferred drugs.

72. If a drug is excluded from a formulary and listed as "not covered," Part D patients will either not have coverage for that drug at all, or will have coverage only if their doctor files a successful appeal with the plan seeking an exception for the patient. In order for an appeal to be granted, the physician must typically establish (i) failure of the preferred drug (*e.g.*, Restasis) to effectively treat the patient's condition, or (ii) the patient's inability to tolerate the side effects or other problems caused by the preferred drug. These grounds for appeal must be satisfied even if, as is the case here, the preferred drug is clinically inferior and has a greater incidence of painful side-effects, such as ocular burning.

73. The paperwork required for the appeal can be detailed and lengthy. In addition, it can take several days before the plan rules on the appeal. If the plan denies the appeal, the patient can appeal the denial to CMS. Regardless, the time, effort, and expense required to successfully navigate this long and burdensome path to payment can often discourage both physicians and patients alike. Often, they simply give up.

74. Even if the plan does grant the appeal or CMS reverses the plan's denial of the appeal, the patient will still need to make a copayment for the drug that is typically many times

more than the copayment for a preferred drug on the same Part D plan formulary. In cases where Xiidra is "not covered," patients can expect to have a copayment that is ***two to five times higher*** than would be the case if Xiidra were on the formulary as a "preferred" drug, as Restasis is for the major Part D plans.

75. Similarly, if a drug is listed on a formulary as "non-preferred," then the patient will also need to make a copayment for the drug that is typically many times more than the copayment for a preferred drug on the same Part D plan formulary. In cases where Xiidra is "non-preferred," patients can expect to have a copayment that is ***two to five times higher*** than would be the case if Xiidra were on the formulary as a "preferred" drug, as Restasis is for the major Part D plans.

76. The cost to the Part D plan of reimbursing covered drugs depends on the current wholesale acquisition cost ("WAC") price of the drug. If the drug price increases, the cost of reimbursement for the plan increases.

77. Pharmaceutical companies generally maintain multi-year rebate agreements with administrators of Part D plans, but negotiate annually with them to gain placement of their drugs on the plans' formularies for the coming year. These negotiations typically begin in or around April of the preceding plan year and culminate in August of the same year when the plans finalize their formularies for the coming year.

78. In these negotiations, Part D plans are typically interested in several key terms to minimize their own costs stemming from listing a drug on their formulary by effectively reducing their cost of reimbursement. One key term is the rebate the pharmaceutical company will provide to the plan on a portion of the drug reimbursement, thereby offsetting the amount of the plan's reimbursements to pharmacies for the sale of that drug to Part D patients.

79. Another key term is "price protection," which refers to rebates pharmaceutical companies offer to a plan to offset any increase to a drug's price during the period for which the drug is listed on the plan's formulary. If the pharmaceutical company raises the WAC price on a drug during the contract term, the "price protection" rebate will simply mirror the incremental increase in price. That rebate thereby cancels out the price increase so that the plan continues to incur the same reimbursement costs for the drug (net of rebates). Without such contractual protection in place, an increase in the price of a given drug would require the plan to incur additional reimbursement costs.

80. Pharmaceutical companies typically contract with third party agents to oversee negotiations with plans for placement of their drugs on the plans' formularies. This practice ensures that the pharmaceutical company keeps its dealings with Part D plans separate from its dealings for commercial business.

81. Some Part D plans delegate their negotiation and selection process to larger administrators. For instance, several of the top ten Part D plans and many smaller ones use another top ten plan (identified as "Plan 3" below) to negotiate and administer their formulary coverage. Plan 3, therefore, has the ability to negotiate with pharmaceutical companies on behalf of multiple Part D plans. There are, thus, fewer negotiation opportunities for pharmaceutical companies than there are Part D plans.

Allergan's Part D Product Portfolio

82. Allergan manufactures, markets, and sells many products other than Restasis that are covered by Part D. These products are referred to herein as "Allergan's Part D product portfolio."

83. As of 2016, Allergan's Part D product portfolio included at least [redacted] products:

[redacted]

[redacted]. Shire is informed and believes, and therefore alleges, that Allergan's Part D portfolio (and the sales and rebates associated with it) stayed the same or grew in 2017 and 2018.

84. Among the products in Allergan's Part D product portfolio are three glaucoma drugs – Lumigan, Combigan, and Alphagan P.

85. The FDA approved Lumigan (bimatoprost ophthalmic solution, 0.01%) on August 31, 2010. Lumigan is used for the reduction of high eye pressure, also called intraocular pressure ("IOP"), in people with open angle glaucoma or ocular hypertension. No generic substitute for Lumigan has been approved for sale in the U.S.

86. Combigan (brimonidine tartrate/timolol maleate ophthalmic solution, 0.2%/0.5%) is a twice-daily solution that the FDA approved on October 30, 2007. The drug is approved for reducing elevated IOP in patients with glaucoma or ocular hypertension. Combigan is recommended for those who require additional or adjunctive IOP-lowering therapy. It lowers IOP slightly less than taking both brimonidine tartrate three times a day and timolol maleate two times a day. No generic substitute for Combigan has been approved for sale in the U.S.

87. Alphagan P (brimonidine tartrate ophthalmic solution, 0.1%/0.15%) is indicated for reducing elevated IOP in patients with glaucoma or ocular hypertension. The FDA approved Alphagan 0.15% on March 16, 2001 and Alphagan 0.1% on August 19, 2005. No generic substitute for Alphagan P has been approved for sale in the U.S.

88. According to publicly available price and sales information, for four recent quarters (Q3 of 2016 through Q2 of 2017), Allergan's three glaucoma drugs alone accounted for almost $750 million of Allergan's sales to Part D plans, while Restasis accounted for another $719 million of sales to Part D plans. The rebates paid to Part D plans for Allergan's three glaucoma drugs were [redacted] in 2016. Thus, the glaucoma drugs alone provide Allergan with more than enough financial wherewithal to give the plans discounts and rebates that far exceed anything that Shire could offer on Xiidra (including giving it to the plans "for free").

89. Overall, Allergan paid Part D plans [redacted] and those payments appear to have continued and even increased in 2017 and 2018. The sheer magnitude of the rebates Allergan has paid, and will continue to pay, Part D plans renders the plans unable to forego these rebates in order to provide formulary access to competing products. As a result, Allergan has immense leverage in its Part D negotiations, allowing it to offer Restasis to the Part D plans at an effective price that is below Allergan's average variable cost.

Shire's Part D Product Portfolio

90. Shire does not have a Part D product portfolio from which it can offer a bundle of discounts and rebates to compete with Allergan. Between 2016 and 2018, Shire's total Part D product portfolio consisted of between [redacted] products: [redacted]. Shire's Part D portfolio has averaged [redacted] in annual sales and [redacted] in annual rebates. This is in stark contrast to Allergan's [redacted] in Part D sales and [redacted] in Part D rebates. That is more than a [redacted] disparity in favor of Allergan. The rebates paid by

Allergan on its three glaucoma drugs alone [redacted] are more than [redacted]

[redacted].

91. Rebates offered and paid to Part D plans apply only to Part D sales and cannot be applied to or combined with rebates offered and paid to commercial plans. Therefore, a pharmaceutical company, such as Allergan, can – and does – maximize its leverage over Part D plans arising from a vast Part D product portfolio. In contrast, a company such as Shire, that does not have a substantial presence in Part D, cannot leverage its much smaller Part D portfolio rebates to effectively compete with Allergan for Part D formulary placement. And it cannot leverage its commercial rebates to bridge that gap.

Allergan's Dominance of DED Drugs Available Through Medicare Part D

92. After receiving FDA approval for Xiidra, Shire entered negotiations with commercial insurance plans for the placement of Xiidra on their formularies. To date, within less than three years since its launch, Xiidra is available on plan formularies that cover around 87 percent of all patients who are enrolled in commercial plans. In terms of total DED prescriptions dispensed to commercial plan beneficiaries, Xiidra commands approximately a 38 percent market share.

93. But for Allergan's anticompetitive scheme, Shire would have achieved success in the Part D market similar to or greater than its success in the commercial market, particularly given that Part D beneficiaries are disproportionately affected by DED compared to the rest of the U.S. population.

94. Xiidra's approval threatened Allergan, so it sought to make it impossible for Xiidra to compete with Restasis in the Part D market. Cognizant of both Restasis' inability to compete head-to-head with clinically superior Xiidra and Shire's willingness and ability to compete on financial terms (limited, of course, by its relatively small portfolio of Part D drugs),

Allergan chose to prevent Shire from gaining share in the Part D market by engaging in an ongoing, overarching, anticompetitive scheme that uses bundling and exclusionary agreements to substantially foreclose Xiidra from the Part D market, to ensure that plans would give preferred status to Restasis, and to directly or indirectly exclude Xiidra from Part D formularies. Allergan has successfully executed these tactics and will continue to do so unless enjoined by the Court.

95. Allergan's internal communications conclusively establish that [redacted] The sample of emails below shows that Allergan [redacted]

- [redacted]
- [redacted]
- [redacted]

- [redacted]
- [redacted]

96. Despite aggressive financial offers and a clinically superior product, Shire has not been and will not be able to gain Xiidra's inclusion on the formularies of Part D plans covering a substantial share of Part D patients due to Allergan's predatory and exclusionary conduct. Shire is unable to offer sufficient discounts (rebates and price protection) on Xiidra and other Shire drugs offered for placement on Part D plans' formularies to offset the loss of Allergan discounts that Part D plans would incur if they were to place Xiidra in a preferred formulary position.

97. Allergan actively touts to investors and analysts its dominance of prescription DED treatments for Part D, including the exclusion of Xiidra on most Part D formularies.

98. Upon information and belief, Allergan's CEO, Brent Saunders, even boasted to investors at a June 2017 investor meeting in Toronto that Allergan has blocked Shire from the Part D market. [redacted].

99. Likewise, in an early May 2017 Allergan Q1 2017 earnings call, Chief Commercial Officer and Executive Vice President, William Meury, stated:

> As it relates to formulary coverage, roughly 40 percent of Restasis and other dry eye products will run through Medicare Part D. And today, we have 95 percent coverage . . . my sense is that once we complete negotiations for Part D, the picture in '18 is going to look comparable and as good as 2017. And so we're exactly where we want to be as it relates to Restasis.

Allergan sent clear expectations to the market that Restasis would retain a "comparable" dominant share in Part D going forward beyond 2018, and it has. This means that there is no hope of a competitive market for prescription drugs to treat DED in Part D for the future, as Allergan has and will simply continue its anticompetitive tactics through future negotiation cycles for Part D formulary contracts to keep Xiidra from being listed on Part D formularies for years to come.

100. Allergan's average variable cost to produce its DED drug, Restasis, is proprietary information which is not available to Shire. Shire, however, is an equally efficient producer of its own DED drug, Xiidra, and has been told by Part D plans that even if Shire gave Xiidra to Part D plans "for free," it could not make up for the plans' loss of rebates across Allergan's Part D product portfolio. Based upon this information, and the fact that Allergan has, at a minimum, three glaucoma products listed on Part D formularies (representing over $1.4 billion in annual Part D sales) that Allergan can use to leverage and finance its anticompetitive scheme, Shire believes, and therefore alleges, that Allergan, as part of a bundled portfolio of products, is providing Restasis to Part D plans at a cost that is below Allergan's average variable cost for Restasis.

101. Allergan has implemented its overarching and interconnected scheme of anticompetitive tactics to substantially foreclose Xiidra from the Part D market that includes a mix of bundled discounts, exclusive contracts, interference and coercion to prevent the inclusion of Xiidra on Part D formularies, and/or the placement of Xiidra in a non-preferred tier on Part D formularies. The main pillars of this scheme for six of the largest Part D plans, which have continuously blocked Xiidra from Part D formularies since its launch in 2016, are described in detail below.

102. Plan 1 is responsible for around 25 percent of DED drug prescriptions under Part D. The negotiations detailed below were between Shire and representatives of Plan 1 who presented themselves as having the authority to speak for and on behalf of Plan 1, and whom Shire understood to have that authority.

103. During the 2017 negotiations (for 2018 formulary placement), Shire offered separate, substantial rebates and discounts off of WAC – for an exclusive formulary listing, for an equal listing with Restasis (parity), and for a non-preferred listing – to Plan 1 to have Xiidra placed on its formulary. In response, Shire was told by Plan 1's Senior Director of Formulary Development and Forecasting for Medicare & Retirement that any placement of Xiidra on its formulary in any capacity would result in the loss of rebates from Allergan. When Shire offered to provide even larger rebates and discounts, the Senior Director stated "[y]ou could give [Xiidra] to us for free, and the numbers still wouldn't work."

104. When Shire continued to press Plan 1 for placement on its formulary, Shire was told that the plan needed Allergan's "permission" to do so. Finally, Plan 1 relented and put Xiidra on its formulary, but only on a "non-preferred" tier, which resulted in copayments for Plan 1's participants that were ***two to five times higher*** than if Xiidra was on the formulary as a "preferred" drug, as Restasis is for Plan 1. This relegated Xiidra to, at best, a high single or low double digit share of Plan 1's participants and has resulted to date in Shire losing sales and profits for Xiidra that Shire would have obtained but for Allergan's anticompetitive conduct.

105. The 2018 negotiations (for 2019 formulary placement) followed the same course. Shire substantially improved its Part D offer to Plan 1 by offering the same discount off of WAC as it had for exclusive placement even if Plan 1 included Xiidra (in the preferred tier) as one of

two DED treatments with a step-through requirement, *i.e.*, a patient would have to try and fail Restasis before being prescribed Xiidra. But that was still not enough.

106. Undeterred, in May 2018, Shire's Senior Vice President for Market Access discussed this offer with Plan 1's Vice President and Senior Director of Industry Relations in an in-person meeting. Shire's Senior Vice President was told by Plan 1's Vice President that the plan once again needed to get Allergan's permission to allow Xiidra on its formulary. That Vice President next told Shire that the plan had gone back to Allergan, that Allergan would not relax its exclusivity requirement, and that Allergan would not allow Xiidra on the plan's formulary (even with a step-through requirement). It is notable that the Plan 1 executive had to ask Allergan – and not his or her superiors at Plan 1 – if Xiidra could be listed on the Plan 1 formulary. Negotiations in early 2019 (for 2020 formulary placement) were again futile. Shire offered Plan 1 the same aggressive discount off of WAC for placement of Xiidra on Plan 1's Part D formulary as one of two DED treatments with a step-through requirement. Plan 1 then ran its financial models on Shire's offer and Plan 1's Senior Director informed Shire that its proposed discount simply "can't work" in light of the bundled rebates across the Allergan product portfolio that Plan 1 would lose in the event it accepted Shire's bid. The Senior Director also reiterated that, in any event, Allergan's terms would not allow Xiidra's placement on Plan 1's Part D formulary, even with a step-through requirement.

108. Based upon the actions and statements of Plan 1, Shire believes, and therefore alleges, that in exchange for substantially excluding Xiidra from the formulary, Allergan has provided Plan 1 with the following benefits: (i) payment of substantial, bundled rebates and discounts across the Allergan Part D portfolio, and (ii) price protection for Allergan's Part D portfolio. However, if Plan 1's formulary includes Xiidra in any capacity other than "non-

preferred," the plan will lose the price protection, rebates, and discounts on the ***entirety*** of Allergan's Part D portfolio. This makes it impossible for Shire to offer discounts on Xiidra that compete with the bundled rebates provided by Allergan and keep Xiidra's price above its cost. This has resulted in Plan 1's participants losing access to a superior product (Xiidra) and paying a higher total cost for an inferior product (Restasis). Shire has also lost, and will continue to lose, sales and profits for Xiidra that would have been dispensed to Plan 1's participants.

109. Plan 2 is responsible for approximately 11 percent of DED drug prescriptions under Part D. The negotiations detailed below were between Shire and representatives of Plan 2 who presented themselves as having the authority to speak for and on behalf of Plan 2, and whom Shire understood to have that authority.

110. During the 2017 negotiations (for 2018 formulary placement), Shire also offered separate, substantial rebates and discounts off of WAC to Plan 2 for an exclusive formulary listing and for parity with Restasis. Shire was told, however, that Plan 2's contract with Allergan provided for price protection from 2014 and bundled rebates with its other drugs on Plan 2's formulary. As a result, Plan 2's Vice President of Trade Relations told Shire that it could not put any other DED drug on its formulary without losing all of its price protection and rebates for all of those drugs. When Shire offered to provide even larger rebates and discounts, that Vice President said that Shire could not pay it enough in rebates to make up for what it would lose if it lost the Allergan rebates and price protection.

111. When Shire continued to press Plan 2 to be placed on its formulary, it was told that Plan 2 would need to check with Allergan and get its permission. Shortly thereafter, the same Plan 2 Vice President told Shire that CMS had just reviewed its formulary and told the plan that it could not exclude Xiidra from its formulary because the plan's therapeutic categories are

based on designations established by the American Hospital Formulary Service ("AHFS") which, unlike other compendia CMS relies upon for formulary classifications, do cover Xiidra. Consequently, Plan 2 listed Xiidra on its formulary, but only as a non-preferred drug that would require a prior authorization and a step through Restasis. Thus, Plan 2 participants had to first try Restasis and experience "failure" before Plan 2 would pay for their prescriptions for Xiidra.

112. Plan 2's 2018 placement of Xiidra on its formulary as "non-preferred" with prior authorization and step through requirements effectively put Xiidra in the same position that it would be in if it was "not covered." In addition, Plan 2's beneficiaries had to make copayments that were ***two to five times higher*** than if Xiidra was on the formulary as a "preferred" drug, as Restasis is for Plan 2. This relegated Xiidra to a high single digit share of Plan 2's participants and resulted in Shire losing sales and profits for Xiidra in 2018 that Shire would have obtained but for Allergan's anticompetitive conduct. Moreover, even Xiidra's "non-preferred" status on Plan 2's formulary was tenuous. When Plan 2 told Allergan about CMS's review and its instruction to Plan 2 to include Xiidra on its formulary due to the AHFS designation, Allergan agreed, reluctantly, to honor the terms of its contractual rebates in 2018. However, Allergan also demanded that Plan 2 rely upon the National Council for Prescription Drug Programs ("NCPDP") formulary classifications in future years because the NCPDP classifications would not require Plan 2 to place Xiidra on its formulary. By using NCPDP's therapeutic categories, Plan 2 would be able to exclude Xiidra in accordance with its exclusive contract with Allergan, undermine CMS' direction, and further Allergan's exclusionary scheme for the future.

113. In 2018, Plan 2 did as it was told by Allergan and made this precise change in its formulary classification, resulting in the plan dropping Xiidra off formulary altogether and providing Restasis with the exclusivity that Allergan demanded. Consistent with this change and

the unyielding threat of losing rebates across Allergan's Part D product portfolio, Plan 2 refused to consider any offer to place Xiidra on a preferred tier during the 2018 negotiation cycle.

114. Based upon the actions and statements of Plan 2, Shire believes, and therefore alleges, that in exchange for excluding Xiidra from the formulary, Allergan has provided Plan 2 with some or all of the following benefits: (i) payment of substantial, bundled rebates and discounts across the Allergan Part D portfolio, and (ii) price protection for Allergan's Part D portfolio. However, if Plan 2's formulary includes Xiidra in a preferred formulary tier, the plan will lose the price protection, rebates, and discounts on the ***entirety*** of Allergan's Part D portfolio. This makes it impossible for Shire to offer discounts on Xiidra that compete with the bundled rebates provided by Allergan and keep Xiidra's price above its cost.

115. Plan 2's refusal to put Xiidra in a preferred position on its formulary, and its subsequent decision to remove Xiidra from its formulary altogether has resulted in Plan 2's participants losing access to a superior product (Xiidra) and paying a higher total cost for an inferior product (Restasis). Shire has also lost, and will continue to lose, sales and profits for Xiidra that would have been dispensed to Plan 2's participants but for Allergan's anticompetitive conduct.

116. "Plan 3" refers to four separate plans which are negotiated jointly through one administrator and which are collectively responsible for over 37 percent of DED drug prescriptions under Part D. Each of the four plans is in the top ten Part D plans. The negotiations detailed below were between Shire and representatives of Plan 3 who presented themselves as having the authority to speak for and on behalf of Plan 3, and whom Shire understood to have that authority.

117. In an initial discussion with Plan 3 during the 2017 negotiations (for 2018 formulary placement), Shire requested parity with Restasis on the plan's formulary with substantial discounts and rebates. In response, the plan stated that it did not want parity, and was only interested in an exclusive listing. Shire asked if the plan was concerned that switching to Xiidra would be too disruptive to the plan. The plan replied that it had no such concern.

118. Shire then offered Plan 3 long-term and even more substantial price protection, discounts, and rebates, and was told unequivocally by Plan 3's Vice President of Trade Relations that "you give us that number and you'll get it [the listing on the plan's formulary]." So Shire gave the plan "that number." Shire then reconfirmed this agreement with that same Vice President, who said that the existing number "will get it done." Out of an abundance of caution, Shire asked if there was any reason at all why Shire may need to increase or improve its offer in any way. The Vice President said no and continued to assure Shire that there was no need to increase or improve the offer.

119. Upon information and belief, Plan 3 then consulted with Allergan about whether Xiidra could be added to its formulary. It is notable that the Plan 3 executive had to ask Allergan – and not his superiors at Plan 3 – if Xiidra could be listed on the Plan 3 formulary.

120. The next time that Shire heard from Plan 3 was a call on or about August 1, 2017 among Shire's Senior Vice President and Head of Global Market Access, Plan 3's Vice President of Trade Relations, and Plan 3's Director of Trade Relations for Medicare Part D, among others. Shire was told that, in stark contrast to the plan's earlier statements, Xiidra could not be added to its formulary (at any tier) because doing so would create "too much disruption." When Shire's Senior Vice President pushed back and asked for reconsideration, he was told by the Plan 3 Vice President that Allergan's contract with the plan would not allow Xiidra or any other DED

treatment on the formulary. When asked "how do we get out" of this position in the future, that Plan 3 Vice President pointedly replied "you don't."

121. Plan 3's conclusive "you don't" meant that Xiidra was permanently excluded from the contracting process. This was confirmed by the 2018 negotiations (for 2019 formulary placement), during which Plan 3 refused to even consider placing Xiidra on its formulary, even though Shire made at least two substantial offers for preferred Xiidra status on its 2019 formularies.

122. To find out why Plan 3 summarily rebuffed Shire for the second consecutive year, Shire's Senior Vice President met with Plan 3's Director of Trade Relations for Medicare Part D during the Pharmaceutical Care Management Association meeting in Orlando in March 2018 to discuss those offers. At that meeting, Plan 3's Director confirmed that Plan 3 could not include Xiidra on formulary because the terms of Plan 3's agreement with Allergan left no way for Plan 3 to place Xiidra on its formulary. The Allergan rebates Plan 3 stood to lose if it placed Xiidra on its formulary simply posed too great a threat to Plan 3 regardless of the terms Shire proposed. Allergan's ongoing, exclusionary conduct has prevented Plan 3 from even considering Shire's offers for Xiidra's formulary placement during the years to come.

123. During the 2018 negotiations, Plan 3 did tell Shire that Plan 3 might consider Shire's offer when and if a generic version of Restasis launches. At this time, no generic version of Restasis has been approved by FDA, much less launched.

124. Based upon what information is available to Shire and what it has been told by Plan 3, Shire believes, and therefore alleges, that Allergan has entered into an anticompetitive exclusive dealing agreement with Plan 3 to exclude Xiidra from Plan 3's formulary and thereby deny Plan 3's participants access to Xiidra. This anticompetitive exclusive dealing arrangement

substantially forecloses competition not only on its own due to the multiple Part D plans it covers and the market share they represent, but also because it is an integral part of Allergan's overall anticompetitive scheme magnifying the arrangement's foreclosure effect upon competition in the market for prescription drugs for the treatment of DED available through Part D.

125. Plan 3's refusal to place Xiidra on its formulary has forced and will force its participants to file appeals to try to get coverage for Xiidra and has required and will require them to endure "step through" treatment with Restasis (whether or not it is the best treatment for them). As a result, Plan 3's participants will either not get coverage for Xiidra, or will need to make copayments that are ***two to five times higher*** than if Xiidra was on the formulary as a "preferred" drug, as Restasis is for Plan 3. This will relegate Xiidra to, at best, a high single or low double digit-share of Plan 3's participants.

126. While patient disruption was the stated reason for Plan 3's withdrawal from an agreement with Shire to list Xiidra on its formulary, upon information and belief, the primary reason that motivated Plan 3's conduct was furtherance of Allergan's goal to exclude Xiidra from the market for prescription drugs for the treatment of DED available through Part D.

127. Shire, therefore, cannot obtain a listing for Xiidra on those plans' formularies regardless of the discounts or rebates it offers and will be excluded from those formularies in the future. This has resulted in Plan 3's participants losing access to a superior product (Xiidra) and paying a higher total cost for an inferior product (Restasis). Shire has also lost, and will continue to lose, sales and profits for Xiidra that would have been dispensed to Plan 3's participants but for Allergan's anticompetitive conduct.

128. The financial terms Shire offered to the Part D plans in 2017, 2018, and 2019 (to date), including discounts, rebates, and price protection terms, far exceeded the discount rates on

Xiidra Shire successfully offered to, and were accepted by, commercial prescription drug plans (where Shire holds approximately a 38 percent market share) to secure preferred formulary placement. Despite Shire's comparatively more attractive offers, the Part D plans declined to list Xiidra on a preferred formulary tier or at all, further illustrating that Allergan is employing and will continue to employ anticompetitive measures to exclude Xiidra from the Part D market for prescription DED treatments.

129. The plans' actions and comments to Shire reflect the coercive and long-term nature of Allergan's conduct, and show that the plans had no choice but to exclude Xiidra from their formularies. First, the comments reflect that the plans' decisions to list Restasis on their formularies were the result of more than just Allergan offering a better price or otherwise competing on the merits. In fact, they make it clear that price and competition had nothing to do with the plans' decisions (*e.g.*, "[y]ou could give [Xiidra] to us for free, and the numbers still wouldn't work"). Second, the comments reflect that Allergan's scheme extends into the future (*e.g.*, Shire: "how do we get out [of this position in the future];" Plan 3: "you don't"), as does their conduct in refusing to list Xiidra on their Part D formularies for the same reasons after two consecutive contract cycles. Despite the fact that Part D contracts are negotiated annually, Allergan's scheme is pervasive and on-going and has ensured and will continue to ensure that Shire has no real possibility of securing formulary placements with these plans as a result of future negotiations.

130. These are but three examples of Allergan's overarching and interconnected scheme of anticompetitive tactics, which have harmed Part D patients and successfully blocked Shire's access to the Part D market, as Allergan's CEO boasted they would. Nonetheless, they leave no doubt that Allergan has used these tactics to put the plans in a position where they

cannot place Xiidra on their formularies – irrespective of the terms that Shire may offer – because they cannot afford to lose the rebates and price protection on the other Allergan products against which Shire does not compete.

131. Shire does not have a Part D product portfolio from which it can offer a bundle of discounts and rebates to compete with Allergan. Between 2016 and 2018, [redacted].

132. Together, Plan 1, Plan 2, and Plan 3 represent over 70 percent of the Part D prescriptions for DED treatment and 90 percent of prescriptions dispensed to participants of the top ten Part D plans. Outside of the top ten plans are nearly 300 small and regional plans, including over 200 that account for 0.1 percent or less of Part D prescriptions for DED treatment and none that exceeds 1 percent. By substantially foreclosing Shire from the top ten plans, Allergan has substantially foreclosed the most effective and efficient means of gaining access to the Part D market for DED treatments, is effectively blocking Shire from competing in that market, and is directly causing financial harm to Shire.

133. Even though Xiidra entered the market in 2016 after the negotiations with Part D plans were completed for the 2017 contract year, Shire requested that the plans discussed above add Xiidra to their formularies at parity with Restasis as a preferred drug for 2017. None of them would do so.

134. Allergan's interactions with Plan 1, Plan 2, and Plan 3 are interconnected and designed to achieve Allergan's publically-announced goal of "blocking" Xiidra from the Part D market. Allergan's actions do not reflect competition on the merits, but an anticompetitive effort

to deny DED patients access to a therapeutically superior and more cost effective DED medication. Indeed, as a result of Allergan's overarching scheme, only a small percentage of Part D plan participants have unrestricted access to Xiidra, or will have access to Xiidra in the future. Allergan's anticompetitive scheme harms competition, injures Part D patients with DED, and causes Shire to lose Xiidra sales.

135. In addition to denying Part D patients access to Xiidra, a superior drug for the treatment of their DED, and in contrast to the commercial plan market in which Xiidra's entrance has increased sales of both Xiidra and Restasis, Allergan's scheme will stunt the growth of the Part D market for DED treatments because Restasis does not treat the vast majority of the signs and symptoms that afflict DED patients. If Allergan's unlawful conduct is permitted to continue, physicians and patients will also become conditioned to prescribe and use only Restasis, relegating Xiidra to a very small segment of the Part D market for DED prescription drugs, and effectively eliminating competition in that market.

136. The discounts that Allergan provides through rebates and price protection benefit Part D plans, but not Part D patients with DED. As a result of Allergan's anticompetitive discounts and rebates, those patients are forced to take an inferior drug that imposes higher costs on them due the exclusion of Xiidra from Part D formularies.

137. Allergan's exclusion of Xiidra from Part D plans covering a substantial share of Part D beneficiaries has caused and will cause injury to Part D patients with DED. That same conduct has also caused and will continue to cause Shire to lose hundreds of millions of dollars in sales and profits from within the market for prescription drugs for the treatment of DED available through Part D.

RELEVANT MARKETS AND ALLERGAN'S MONOPOLY POWER

138. Allergan possesses and has possessed at all relevant times, monopoly power in the market for prescription drugs for the treatment of DED available through Part D. Allergan sells the dominant DED treatment in the Medicare Part D market under the brand name Restasis. But for Allergan's conduct, Xiidra would meaningfully constrain Allergan's monopoly power, which is represented by Restasis in the Medicare Part D market.

Relevant Product Market – Prescription Drugs for the Treatment of DED Available Through Medicare Part D

139. The market for prescription drugs for the treatment of DED available through Medicare Part D is a properly defined product market.

140. There are no other medical or other reasonably available substitutes for prescription drugs to treat DED. Over-the-counter treatments, such as artificial tears, are only palliative treatments and do not treat the underlying inflammation that causes DED. At best, over-the-counter treatments help moisten the eyes and provide temporary symptom relief. Similarly, punctal plugs (small medical devices that are inserted into the tear ducts to block them) offer only temporary relief and do not treat the underlying disease. DED is a serious, progressive disease, and failure to treat it appropriately could lead to increased inflammation, significant damage to the eye (such as corneal infection and scarring), and complications including vision loss. Thus, for those patients with DED, prescription drugs to treat DED are their only option.

141. Commercial prescription drug plans are not substitutes for Part D plans from the perspective of both Part D patients and sellers of DED drugs. Part D serves a distinct group of consumers for whom commercial plans would not be an option. Congress added Part D to provide prescription drug coverage to those aged 65 and older (and those under age 65 with

permanent disabilities) for whom commercial insurance is either too expensive or would not provide comprehensive coverage. Accordingly, Part D plans typically have lower premiums than commercial plans because the federal government subsidizes a substantial portion of each Part D participant's premium. And unlike commercial prescription plans, CMS reviews and approves each Part D plan to verify that the plan is providing access to an acceptable range of Part D drug choices. This is because Part D formularies are subject to certain statutory requirements that commercial formularies are not. Part D plans must offer prescription drug coverage as prescribed by the Medicare Prescription Drug, Improvement, and Modernization Act or the plan must be approved by the Secretary of Health and Human Services. Moreover, Part D participants would not, and in most cases could not, look to commercial insurance as an alternative to avoid the anticompetitive harm inflicted on them by Allergan's manipulation of their Part D formularies. Because of these differences in cost and benefits, Medicare beneficiaries using Part D do not consider a commercial plan to be an adequate alternative.

142. Allergan, Shire, and other industry participants recognize prescription drug plans available under Medicare Part D as distinct from prescription drug plans offered through commercial plans, as is shown by the example of internal Allergan emails quoted in Paragraph 95 above. Pharmaceutical companies, therefore, have separation between the business that they conduct with Medicare Part D plans and the business that they conduct with commercial plans. Pharmaceutical companies often use different staff, or hire a third party, to negotiate with Part D plan administrators even though many of those administrators also manage commercial formularies.

143. The contracting cycle for Part D plans is also different from commercial plans. To gain access to a Medicare formulary, pharmaceutical companies begin negotiations with Part

D plans in or around April and the negotiations end in August of the same year to allow time for CMS review and approval, where commercial plans are open to negotiations all year. Pharmaceutical companies also separately monitor and report their Medicare Part D sales and financial performance.

144. Many of these differences are also true for administrators of Part D plans. Part D plans keep their Medicare business separate from their commercial business, and they also separately monitor and report their Part D sales and financial performance. In particular, the rebates offered and paid to commercial plans and Part D plans are distinct, and commercial plans are unable to use Part D plan rebates to negotiate a better deal for themselves with the pharmaceutical companies.

Relevant Geographic Market – United States

145. The relevant geographic market is the United States. Drugs require FDA approval before they can be sold in the United States. Thus, drugs sold outside of the United States are not alternatives to Part D beneficiaries. Also, Part D plans are available throughout the United States.

Allergan Exercises Monopoly Power in Prescription Drugs for the Treatment of DED Available Through Medicare Part D

146. Restasis was the only prescription treatment for DED available in the United States until Xiidra's launch in 2016. Despite Xiidra's launch, Restasis has retained a dominant market share in the treatment of DED for Part D. While Xiidra has made inroads in the commercial market, it has not meaningfully constrained Allergan's sales in the Part D market. For example, Xiidra has successfully captured approximately a 38 percent market share with the commercial plans two years post launch, but has gained just around a 13 percent market share with the Part D plans post launch.

147. Beyond Allergan's Restasis market share, Allergan's monopoly power is evidenced by the barriers to entry into the relevant market.

148. Substantial barriers to entry exist for prescription DED drugs. High fixed costs, difficult regulatory hurdles, and complex manufacturing processes render the entry of any new competitor difficult. Potential new drug competitors need to conduct expensive trials to obtain FDA approval. A recent analysis by the Tufts Center for the Study of Drug Development, published in the Journal of Health Economics in March of 2016, calculates the average cost to develop and gain marketing approval for a new drug to be $2.558 billion. The study noted that drug development is lengthy – often taking longer than a decade – and that out-of-pocket costs for individual drugs and higher failure rates for drugs tested in clinical trials were the primary reasons behind rising drug development costs. FDA requirements also make it very difficult for a prescription drug treatment for DED to receive approval today. Indeed, the approval path for Restasis took three years and included multiple rejections from the FDA, and, due to increased regulatory scrutiny, it would be even more difficult for Restasis to be approved today. Because of these changes in FDA standards, Xiidra had to meet a much more stringent approval criteria for safety and efficacy than Restasis did.

ALLERGAN'S ANTICOMPETITIVE SCHEME HARMS COMPETITION AND INJURES CONSUMERS

Allergan Has Entered and Will Continue to Enter into Exclusionary Contracts with Part D Plans

149. Allergan has entered and will continue to enter contracts with plans covering over 70 percent of the Part D prescription DED treatment market, and is engaged in an overarching and interconnected anticompetitive scheme to maintain its monopoly power in the Part D DED treatment market.

150. For instance, Allergan has entered into agreements with Part D plans that condition bundled rebates for Allergan's Part D portfolio on the complete or near complete exclusion of Xiidra from that plan's formulary.

151. Allergan has combined its bundled rebate agreements with contracts with Part D plans that require Restasis' exclusive formulary listing such that the plans are prevented from covering Xiidra and/or placing Xiidra in a preferred formulary tier.

152. Upon information and belief, Allergan has engaged in further interference to prevent Part D plans from contracting with Shire, even where that plan has already agreed, or agreed in principle, to terms with Shire.

Allergan's Anticompetitive Scheme Forecloses a Substantial Amount of Competition in the Part D Prescription DED Treatment Market and Artificially Maintains Allergan's Market Share and Monopoly Power

153. The culmination of Allergan's conduct is an anticompetitive scheme with the combined effect of substantially foreclosing Xiidra from competing in the Part D prescription DED treatment market, injuring Shire and Part D patients, now and going forward.

154. As a result of Allergan's exclusionary conduct and anticompetitive scheme, Xiidra cannot compete with Restasis on the largest Part D plans, which cover at least 70 percent of Part D prescriptions for DED treatment, causing Shire to lose millions of dollars in sales and profits. The remaining portion of the Part D market is serviced by nearly 300 plans, virtually all of which only cover a small fraction of a percentage point of Part D beneficiaries (*i.e.*, less than 100 DED treatment prescriptions per month). By limiting new entrants, such as Shire, to pursing this small and highly fragmented remainder of the relevant market, Allergan is raising Shire's costs of entry. The elevated costs of approaching and negotiating with hundreds of very small Part D plans has rendered it infeasible for Shire to capture the Part D market share for prescription DED treatments held by those smaller plans.

155. By excluding Xiidra from the largest Part D plans, Allergan has shut Shire out of the most effective and efficient means of accessing the Part D participants and offering them relief from Allergan's monopoly power. This, in conjunction with Allergan's contracts with other Part D plans, will cause Restasis to maintain a market share of approximately 87 percent in the Part D prescription DED treatment market, denying almost all Part D patients with DED access to a superior and lower cost alternative treatment (Xiidra).

156. Allergan's anticompetitive scheme shields large segments of the Part D prescription DED treatment marketplace from competition, thereby stifling competition on the merits and foreclosing Part D patients suffering from DED from any meaningful access to the best treatment available for them. Allergan has used exclusionary bundling contracts and exclusive dealing to coerce Part D plans and to preserve and extend its monopoly power in the Part D prescription DED treatment market.

157. Allergan's conduct also restrains growth in the Part D market for DED medication prescriptions in light of Xiidra's clinical efficacy and the breadth of its approved indication. Were it not for Allergan's exclusionary scheme, more Part D patients suffering from DED, especially the vast majority of those whose DED is not attributable to insufficient tear volume (the only sign of DED Restasis is approved to treat), would benefit from treatment. Service of that unmet need would grow the Part D market for DED medication prescriptions.

158. Absent Allergan's anticompetitive scheme to foreclose and stifle competition in the market for prescription DED medications covered under Part D formularies, Shire would achieve a substantial market presence and pose a far greater competitive threat to Allergan among Part D beneficiaries. Instead, Allergan's anticompetitive conduct has caused Restasis to be unconstrained in the Part D market, which has harmed patients by denying them access to a

superior drug and has harmed Shire by effectively excluding it from the Part D market and causing financial harm to Shire.

Allergan's Exclusionary Conduct Will Artificially Maintain Allergan's Market Share and Monopoly Power in the Part D Prescription DED Drug Market and Lead to Overcharging and Inferior Consumer Choice for Medicare Part D Beneficiaries

159. There is no valid procompetitive business justification for Allergan's exclusionary contracts and anticompetitive scheme. Allergan does not use the contracts, including the bundled rebates, to achieve efficiencies or otherwise benefit consumers and/or competition. In fact, Allergan's contracts do not lower copayments or provide any benefit at all to the Part D patients who actually buy and use Restasis.

160. The effect of Allergan's exclusionary and anticompetitive contracting scheme will be that Part D patients are effectively denied or will have severely limited access to Xiidra, the only drug approved by the FDA for the treatment of ***both*** the signs and symptoms of DED. Part D beneficiaries who are prescribed DED medication can only obtain Restasis under their Part D plan unless they can overcome the restrictions and afford the higher copayments Allergan's terms impose on Xiidra.

161. As a direct result of Allergan excluding Xiidra from the Part D market, Part D patients with DED are being and will be overcharged because (i) they are being forced to make higher copayments for Xiidra because it is a non-preferred or off-formulary drug, (ii) they are getting less value for their copayment amount because Restasis is inferior to Xiidra, and (iii) many patients who purchase and use Restasis must also purchase and use a topical steroid, which makes the cost of treatment with Restasis higher than the cost of treatment with Xiidra.

162. The fact that plans will not list Xiidra on their formularies even if it is "given" to them shows that the plans are deciding to purchase Restasis as a result of Allergan's

exclusionary terms and anticompetitive scheme, not because of the relative prices and merits of Xiidra and Restasis.

163. Allergan's exclusionary conduct and anticompetitive scheme has caused and will cause loss or injury to Part D patients and to Shire and has caused and will cause anticompetitive harm that is not offset by procompetitive benefits.

Shire Is At Least an Equally Efficient Competitor

164. Shire is at least an equally efficient competitor to Allergan. Specifically, Xiidra is a more effective DED drug and serves a broader indication than Restasis. Furthermore, the comparable resources and structure of Allergan and Shire provide no basis to infer that Allergan can manufacture Restasis at a lower cost than Shire can manufacture Xiidra.

165. The FDA approved Xiidra as the first eye drop approved to treat ***both*** the signs and symptoms of DED, purposefully designed and optimized for ocular use. The FDA took the rare step of issuing a press release to mark Xiidra's approval, which industry investors celebrated as a "big game changer." By treating both the signs and symptoms of DED (including inflammation), Xiidra provides a clinically superior treatment and meets an unmet need among DED patients that has not been and cannot be met by Restasis.

166. Allergan and Shire, respectively, list Restasis and Xiidra at the same WAC price, even though Xiidra is a more effective drug with a broader indication.

167. As of the start of 2018, Shire had over 23 thousand employees and products available in over 100 countries. In 2017, Shire had $14.5 billion in net product sales ($15.2 billion total revenue) across seven therapeutic areas, generated $4.6 billion in non-GAAP net income and operated on a 43 percent non-GAAP EBITDA margin. During 2017, Shire continued to focus on its R&D efforts with an investment of $1.8 billion. In 2017, it had 40

clinical development programs in its pipeline including a late stage pipeline with a total of approximately 15 programs in Phase 3 or registration, the most robust rare disease-focused pipeline in the industry.

168. Allergan is a large global pharmaceutical company ($15.8 billion total revenue in 2018, 17 thousand employees). Allergan does not have any advantage in size, breadth or structure that enables it to produce Restasis for less cost than Shire produces Xiidra.

169. In sum, Xiidra has the strongest efficacy profile of any prescription DED drug on the market and Shire is at least as equally efficient a competitor as Allergan. It is, therefore, not possible that Allergan's continued and ongoing dominance of the market for DED drugs available through Part D, and Shire's exclusion from that market, is a result of competitive market forces or Shire's inability to compete head-to-head with Allergan on equal footing. Rather, it is Allergan's anticompetitive conduct that has excluded and will continue to exclude a superior product (Xiidra), harm competition in the Part D market, and injure Part D patients with DED. Shire has also suffered, and will continue to suffer, harm flowing directly from Allergan's anticompetitive conduct.

CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION
MONOPOLIZATION (15 U.S.C. § 2)

170. Shire repeats and realleges each allegation in paragraphs 1 through 169 as if fully set forth herein.

171. Allergan has, and during the relevant period had, a market share of approximately 87 percent in the Part D prescription DED treatment market. Accordingly, and combined with high entry barriers, Allergan possesses monopoly power in the Part D prescription DED treatment market in the United States.

172. Allergan has willfully maintained and will further maintain its monopoly power in this market through exclusionary and anticompetitive means. Allergan is engaged in an ongoing and overarching anticompetitive scheme designed to maintain its monopoly power in the market for prescription drugs for the treatment of DED available through Part D, using a mix of bundled discounts, exclusive contracts, interference, and coercion to prevent the inclusion of Xiidra on Part D formularies. Allergan coerced Part D plans into agreements that give preferred status to Restasis to the exclusion of Xiidra, including through, *inter alia*, bundled rebate agreements in which Allergan provided "price protection" and other rebates or discounts for Allergan's portfolio of Part D products conditioned on the exclusion of Xiidra from formularies, and agreements conditioned on Xiidra being listed, if at all, as a "non-preferred" treatment.

173. By engaging in this conduct, Allergan is abusing and has abused its monopoly power – as opposed to, for example, competing on the merits or having more efficient production or superior product quality – and unfairly impeded competition in the market for prescription drugs for the treatment of DED available through Part D, thereby restraining trade and competition by limiting the public's access to a superior DED prescription treatment.

174. Allergan's unlawful conduct has and will continue to directly and proximately cause injury or loss to interstate commerce and to Part D beneficiaries. Specifically, Part D beneficiaries suffering from DED must incur substantial costs and/or burdens or otherwise forego the opportunity to receive the more effective and thorough drug to treat their DED. Allergan's conduct denies Part D beneficiaries the choice of and access to a better treatment option.

175. Allergan's unlawful conduct further harms competition and thereby causes and threatens injury or loss to Shire's business, property, and competitive position, which will

continue unless Allergan's anticompetitive conduct is enjoined. Specifically, Shire has and will continue to lose millions of dollars in sales and profits from within the market for prescription drugs for the treatment of DED available through Part D that would have taken place but for Allergan's behavior. Shire's injuries are of the type that antitrust laws are intended to prohibit, and flow directly from Allergan's anticompetitive conduct in violation of Section 2 of the Sherman Act.

176. Allergan's conduct violates Section 2 of the Sherman Act, 15 U.S.C. § 2, and Shire is entitled to damages and injunctive relief pursuant to Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15 and 26, and reimbursement of its costs for bringing this action, including its reasonable attorneys' fees.

SECOND CAUSE OF ACTION
ATTEMPTED MONOPOLIZATION (15 U.S.C. § 2)

177. Shire repeats and realleges each allegation in paragraphs 1 through 176 as if fully set forth herein.

178. In the alternative, Allergan is willfully and wrongfully attempting to obtain monopoly power in the Part D prescription DED treatment market. Allergan is willfully engaging in a course of conduct, including anticompetitive and exclusionary actions, with the specific intent of monopolizing this market. Allergan is engaged in an ongoing and overarching anticompetitive scheme designed to obtain monopoly power in the market for prescription drugs for the treatment of DED available through Part D, using a mix of bundled discounts, exclusive contracts, interference, and coercion to prevent the inclusion of Xiidra on Part D formularies. Allergan coerced Part D plans into agreements that give preferred status to Restasis to the exclusion of Xiidra, including through, *inter alia*, bundled rebate agreements in which Allergan provided "price protection" and other rebates or discounts for Allergan's portfolio of Part D

products conditioned on the exclusion of Xiidra from formularies, and agreements conditioned on Xiidra being listed, if at all, as a "non-preferred" treatment.

179. In the alternative, there is a dangerous probability that, unless restrained, Allergan will succeed in obtaining monopoly power in the Part D prescription DED treatment market.

180. By engaging in this conduct, Allergan is unfairly impeding competition in the market for prescription drugs for the treatment of DED available through Part D, thereby restraining trade and competition by limiting the public's access to a superior DED prescription treatment.

181. Allergan's unlawful conduct has and will continue to directly and proximately cause injury or loss to interstate commerce and to Part D beneficiaries. Specifically, Part D beneficiaries suffering from DED must incur substantial costs and/or burdens or otherwise forego the opportunity to receive the more effective and thorough drug to treat their DED. Allergan's conduct denies Part D beneficiaries the choice of and access to a better treatment option.

182. Allergan's unlawful conduct further harms competition and thereby causes and threatens injury or loss to Shire's business, property, and competitive position, which will continue unless Allergan's anticompetitive conduct is restrained by the issuance of injunctive relief. Specifically, Shire has and will continue to lose millions of dollars in sales and profits from within the market for prescription drugs for the treatment of DED available through Part D that would have taken place but for Allergan's behavior. Shire's injuries are of the type that antitrust laws are intended to prohibit, and flow directly from Allergan's anticompetitive conduct in violation of Section 2 of the Sherman Act.

183. Allergan's conduct violates Section 2 of the Sherman Act, 15 U.S.C. § 2, and

Shire is entitled to damages and injunctive relief pursuant to Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15 and 26, and reimbursement of its costs for bringing this action, including its reasonable attorneys' fees.

THIRD CAUSE OF ACTION
AGREEMENTS IN RESTRAINT OF TRADE (15 U.S.C. § 1)

184. Shire repeats and realleges each allegation in paragraphs 1 through 183 as if fully set forth herein.

185. As set forth above, Allergan has employed an ongoing anticompetitive scheme to preserve and extend its monopoly power and prevent competition in the market for prescription drugs for the treatment of DED available through Part D plans. That scheme includes Allergan's agreements with Part D plans with various exclusionary contract terms.

186. Through these anticompetitive agreements, Allergan is precluding its competitor, Shire, from gaining meaningful access to Part D formularies, and avoiding and foreclosing competition in the relevant market.

187. The purpose and effect of these agreements is to substantially foreclose and exclude competition, in particular the competitive threat presented by Shire.

188. Allergan's conduct constitutes an unlawful contract or contracts to exclude competition and unreasonably restrain trade in violation of Section 1 of the Sherman Act. At all relevant times, Allergan's exclusionary agreements will assist Allergan in: (i) effectively excluding superior, competitive products from the market for prescription drugs for the treatment of DED available through Part D; (ii) maintaining Allergan's dominant market share and monopoly power in the market for prescription drugs for the treatment of DED available through Part D; and (iii) otherwise reaping the benefits of its unlawful monopoly power.

189. Allergan's coercive conduct has induced Part D plans to agree that they will

continue to receive rebates on the condition that they not grant formulary access to Xiidra or do so on severely unfavorable terms.

190. There is no legitimate business or procompetitive justification for Allergan's conduct.

191. Allergan's unlawful conduct has and will continue to directly and proximately cause injury or loss to interstate commerce and to Part D beneficiaries. Specifically, Part D beneficiaries suffering from DED must incur substantial costs and/or burdens or otherwise forego the opportunity to receive the more effective and thorough drug to treat their DED. Allergan's conduct denies Part D beneficiaries consumer choice and access to a better treatment option.

192. Allergan's unlawful conduct further causes and threatens injury or loss to Shire's business and property which will continue unless Allergan's anticompetitive conduct is restrained by the issuance of injunctive relief. Specifically, Shire has and will continue to lose millions of dollars in sales and profits from within the market for prescription drugs for the treatment of DED available through Part D that would take place but for Allergan's behavior. Shire's injuries are of the type that the antitrust laws are intended to prohibit, and flow directly from Allergan's anticompetitive conduct in violation of Section 1 of the Sherman Act.

193. Allergan's conduct violates Section 1 of the Sherman Act, 15 U.S.C. § 1, and Shire is entitled to damages and injunctive relief pursuant to Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15 and 26, and reimbursement of its costs for bringing this action, including its reasonable attorneys' fees.

FOURTH CAUSE OF ACTION
MONOPOLIZATION (N.J. Stat. § 56:9-4)

194. Shire repeats and realleges each allegation in paragraphs 1 through 193 as if fully

set forth herein.

195. Allergan is a "person" within the meaning of N.J. Stat. § 56:9-2(a).

196. Restasis is a "commodity" within the meaning of N.J. Stat. § 56:9-2(c), and therefore Allergan's business marketing, selling, and/or distributing Restasis is "trade or commerce" within the meaning of N.J. Stat. § 56:9-2(b).

197. Allergan has, and during the relevant period had, a market share of approximately 87 percent in the Part D prescription DED treatment market. Accordingly, and combined with high entry barriers, Allergan possesses monopoly power in the Part D prescription DED treatment market in the United States.

198. As set forth above, Allergan has willfully maintained and will further maintain its monopoly power in this market through exclusionary and anticompetitive means. Allergan is engaged in an ongoing and overarching anticompetitive scheme designed to maintain its monopoly power in the market for prescription drugs for the treatment of DED available through Part D, using a mix of bundled discounts, exclusive contracts, interference and coercion to prevent the inclusion of Xiidra on Part D formularies. Allergan coerced Part D plans into agreements that give preferred status to Restasis to the exclusion of Xiidra, including, *inter alia*, bundled rebate agreements in which Allergan provided "price protection" and other rebates or discounts for Allergan's portfolio of Part D products conditioned on the exclusion of Xiidra from formularies, and agreements conditioned on Xiidra being listed, if at all, as a "non-preferred" treatment.

199. By engaging in this conduct, Allergan is abusing and has abused its monopoly power – as opposed to, for example, competing on the merits or having more efficient production or superior product quality – and unfairly impeded competition in the market for prescription

drugs for the treatment of DED available through Part D, thereby restraining trade and competition by limiting the public's access to a superior DED prescription treatment.

200. Allergan's unlawful conduct has and will continue to directly and proximately cause injury or loss to New Jersey commerce and to Part D beneficiaries. Specifically, Part D beneficiaries suffering from DED must incur substantial costs and/or burdens or otherwise forego the opportunity to receive the more effective and thorough drug to treat their DED. Allergan's conduct denies Part D beneficiaries the choice of and access to a better treatment option.

201. Allergan's unlawful conduct further harms competition and thereby causes and threatens injury or loss to Shire's business, property, and competitive position, which will continue unless Allergan's anticompetitive conduct is enjoined. Specifically, Shire has and will continue to lose millions of dollars in sales and profits from within the market for prescription drugs for the treatment of DED available through Part D that would take place but for Allergan's behavior. Shire's injuries are of the type that antitrust laws are intended to prohibit, and flow directly from Allergan's anticompetitive conduct in violation of Section 56:9-4 of the New Jersey Antitrust Act.

202. Allergan's conduct violates Section 56:9-4 of the New Jersey Antitrust Act, N.J. Stat. § 56:9-4, and Shire is entitled to damages and injunctive relief pursuant to Sections 56:9-10 and 56:9-12 of the New Jersey Antitrust Act, N.J. Stat. §§ 56:9-10 and 56:9-12, and reimbursement of its reasonable attorneys' fees, filing fees, and reasonable costs of suit.

FIFTH CAUSE OF ACTION
ATTEMPTED MONOPOLIZATION (N.J. Stat. § 56:9-4)

203. Shire repeats and realleges each allegation in paragraphs 1 through 202 as if fully set forth herein.

204. Allergan is a "person" within the meaning of N.J. Stat. § 56:9-2(a).

205. Restasis is a "commodity" within the meaning of N.J. Stat. § 56:9-2(c), and therefore Allergan's business marketing, selling, and/or distributing Restasis is "trade or commerce" within the meaning of N.J. Stat. § 56:9-2(b).

206. As set forth above, in the alternative, Allergan is willfully and wrongfully attempting to obtain monopoly power in the Part D prescription DED treatment market. Allergan is willfully engaging in a course of conduct, including anticompetitive and exclusionary actions, with the specific intent to monopolize this market. Allergan is engaged in an ongoing and overarching anticompetitive scheme designed to obtain monopoly power in the market for prescription drugs for the treatment of DED available through Part D, using a mix of bundled discounts, exclusive contracts, interference and coercion to prevent the inclusion of Xiidra on Part D formularies. Allergan coerced Part D plans into agreements that give preferred status to Restasis to the exclusion of Xiidra, including, *inter alia*, bundled rebate agreements in which Allergan provided "price protection" and other rebates or discounts for Allergan's portfolio of Part D products conditioned on the exclusion of Xiidra from formularies, and agreements conditioned on Xiidra being listed, if at all, as a "non-preferred" treatment.

207. In the alternative, there is a dangerous probability that, unless restrained, Allergan will succeed in obtaining monopoly power in the Part D prescription DED treatment market.

208. By engaging in this conduct, Allergan is unfairly impeding competition in the market for prescription drugs for the treatment of DED available through Part D, thereby restraining trade and competition by limiting the public's access to a superior DED prescription treatment.

209. Allergan's unlawful conduct has and will continue to directly and proximately

cause injury or loss to New Jersey commerce and to Part D beneficiaries. Specifically, Part D beneficiaries suffering from DED must incur substantial costs and/or burdens or otherwise forego the opportunity to receive the more effective and thorough drug to treat their DED. Allergan's conduct denies Part D beneficiaries the choice of and access to a better treatment option.

210. Allergan's unlawful conduct further harms competition and thereby causes and threatens injury or loss to Shire's business, property, and competitive position, which will continue unless Allergan's anticompetitive conduct is restrained by the issuance of injunctive relief. Specifically, Shire has and will continue to lose millions of dollars in sales and profits from within the market for prescription drugs for the treatment of DED available through Part D that would take place but for Allergan's behavior. Shire's injuries are of the type that antitrust laws are intended to prohibit, and flow directly from Allergan's anticompetitive conduct in violation of Section 56:9-4 of the New Jersey Antitrust Act.

211. Allergan's conduct violates Section 56:9-4 of the New Jersey Antitrust Act, N.J. Stat. § 56:9-4, and Shire is entitled to damages and injunctive relief pursuant to Sections 56:9-10 and 56:9-12 of the New Jersey Antitrust Act, N.J. Stat. §§ 56:9-10 and 56:9-12, and reimbursement of its reasonable attorneys' fees, filing fees, and reasonable costs of suit.

SIXTH CAUSE OF ACTION
AGREEMENTS IN RESTRAINT OF TRADE (N.J. Stat. § 56:9-3)

212. Shire repeats and realleges each allegation in paragraphs 1 through 211 as if fully set forth herein.

213. Allergan is a "person" within the meaning of N.J. Stat. § 56:9-2(a).

214. Restasis is a "commodity" within the meaning of N.J. Stat. § 56:9-2(c), and therefore Allergan's business marketing, selling, and/or distributing Restasis is "trade or

commerce" within the meaning of N.J. Stat. § 56:9-2(b).

215. As set forth above, Allergan has employed an ongoing anticompetitive scheme to preserve and extend its monopoly power and prevent competition in the market for prescription drugs for the treatment of DED available through Part D plans. That scheme includes Allergan's agreements with Part D plans with various exclusionary contract terms.

216. Through these anticompetitive agreements, Allergan is precluding its competitor, Shire, from gaining meaningful access to Part D formularies, and avoiding and foreclosing competition in the relevant market.

217. The purpose and effect of these agreements is to substantially foreclose and exclude competition, in particular the competitive threat presented by Shire.

218. Allergan's conduct constitutes an unlawful contract or contracts to exclude competition and unreasonably restrain trade in violation of Section 56:9-3 of the New Jersey Antitrust Act. At all relevant times, Allergan's exclusionary agreements will assist Allergan in: (i) effectively excluding superior, competitive products from the market for prescription drugs for the treatment of DED available through Part D; (ii) maintaining Allergan's dominant market share and monopoly power in the market for prescription drugs for the treatment of DED available through Part D; and (iii) otherwise reaping the benefits of its illegal monopoly power.

219. Allergan's coercive conduct has induced Part D plans to agree that they will continue to receive rebates on the condition that they not grant formulary access to Xiidra or do so on severely unfavorable terms.

220. There is no legitimate business or procompetitive justification for Allergan's conduct.

221. Allergan's unlawful conduct has and will continue to directly and proximately

cause injury or loss to New Jersey commerce and to Part D beneficiaries. Specifically, Part D beneficiaries suffering from DED must incur substantial costs and/or burdens or otherwise forego the opportunity to receive the more effective and thorough drug to treat their DED. Allergan's conduct denies Part D beneficiaries consumer choice and access to a better treatment option.

222. Allergan's unlawful conduct further causes and threatens injury or loss to Shire's business and property which will continue unless Allergan's anticompetitive conduct is restrained by the issuance of injunctive relief. Specifically, Shire has and will continue to lose millions of dollars in sales and profits from within the market for prescription drugs for the treatment of DED available through Part D that would take place but for Allergan's behavior. Shire's injuries are of the type that antitrust laws are intended to prohibit, and flow directly from Allergan's anticompetitive conduct in violation of Section 56:9-3 of the New Jersey Antitrust Act.

223. Allergan's conduct violates Section 56:9-3 of the New Jersey Antitrust Act, N.J. Stat. § 56:9-3, and Shire is entitled to damages and injunctive relief pursuant to Sections 56:9-10 and 56:9-12 of the New Jersey Antitrust Act, N.J. Stat. §§ 56:9-10 and 56:9-12, and reimbursement of its reasonable attorneys' fees, filing fees, and reasonable costs of suit.

SEVENTH CAUSE OF ACTION
TORTIOUS INTERFERENCE WITH BUSINESS RELATIONS

224. Shire repeats and realleges each allegation in paragraphs 1 through 223 as if fully set forth herein.

225. Shire had a reasonable expectation of marketing and selling Xiidra to the market for prescription drugs for the treatment of DED available through Part D by entering into agreements with Part D plans to make Xiidra available to Part D plan beneficiaries. In addition,

Shire had a reasonable expectation of capturing a material share of the market for prescription drugs for the treatment of DED available through Part D once Xiidra was added to the Part D plans' formularies given that Xiidra is a superior means of treating DED with a broader FDA-approved indication than Restasis.

226. Allergan knew that Shire had a reasonable expectation of economic advantage through business relations with Part D plans. Allergan intentionally and wrongfully interfered with Shire's expected business dealings with Part D plans by: (i) providing rebate and/or discount terms to Part D plans covering Allergan's Part D product portfolio which are conditioned on the plans maintaining Restasis as the exclusive DED treatment available on the plans' formularies (or at least its preferred tier) such that the plans would lose the entirety of Allergan's portfolio-wide rebates and/or discounts if they were to offer Xiidra on their formularies in addition to Restasis; and (ii) coercing one or more Part D plans to cease negotiations to add Xiidra to their formularies or, if Xiidra was added, to relegate Xiidra to non-preferred status. Allergan intentionally took such measures to restrain Part D plans from adding Xiidra to their formularies and, thus, effectively exclude Shire from the market for prescription drugs for the treatment of DED available through Part D.

227. As a direct result of Allergan's intentional and wrongful interference, Part D plans have been dissuaded from adding Xiidra to their formularies, or listing Xiidra on the preferred tier of their formularies, thereby destroying Shire's expected business relations with Part D plans for the market for prescription drugs for the treatment of DED available through Part D.

228. But for Allergan's interference, there was a reasonable probability that Shire would receive the economic benefits resulting from its marketing and sale of Xiidra to the market for prescription drugs for the treatment of DED available through Part D and Shire's

capture thereafter of a material share of the market for prescription drugs for the treatment of DED available through Part D.

229. Allergan had no adequate justification to interfere with Shire's business relations with Part D plans. Allergan's conduct is outrageous and against the public interest because Allergan acted with malice and/or reckless indifference to the rights of others.

230. Allergan's interference with Shire's business relations with Part D plans has and will continue to cause Shire to suffer damages, including lost profits and other damages.

231. Upon information and belief, Allergan's acts of tortious interference will continue unless restrained by this Court.

232. Shire is entitled to money damages, injunctive relief, and such other relief as this cause of action allows.

PRAYER FOR RELIEF

WHEREFORE, Shire requests that:

A. The conduct alleged herein be declared, adjudged, and/or decreed to be unlawful under Section 1 and Section 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, and applicable state law;

B. Pursuant to Section 16 of the Clayton Act (15 U.S.C. § 26), and applicable state law, the anticompetitive, predatory and/or exclusionary conduct of Allergan be permanently enjoined;

C. Shire be awarded money damages, trebled pursuant to law;

D. Shire be awarded its costs for bringing this action, including reasonable attorneys' fees; and

E. Shire be awarded such other and further relief as this Court deems just and proper.

Dated: April 25, 2019

By: /s/ *Charles M. Lizza*
Charles M. Lizza
William C. Baton
SAUL EWING ARNSTEIN & LEHR LLP
One Riverfront Plaza, Suite 1520
Newark, New Jersey 07102-5426
(973) 286-6700
clizza@saul.com

Attorneys for Plaintiff
Shire US, Inc.

Of Counsel:

Michael F. Brockmeyer
David S. Shotlander
Amanda J. Hamilton
HAUG PARTNERS LLP
1667 K St. NW, Suite 500
Washington, DC 20006
(202) 292-1530
mbrockmeyer@haugpartners.com

Fred A. Kelly, Jr.
Joshua S. Barlow
HAUG PARTNERS LLP
One Post Office Square
Boston, MA 02109
(617) 426-6800
fkelly@haugpartners.com